



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 11 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Barbara J. Lewandowski
Vident
3150 East Birch Street
Brea, California 92821

Re: K012473

Trade/Device Name: Ceramic Hextop Abutment and SynOcta® In-Ceram Coping
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: June 18, 2002
Received: June 21, 2002

Dear Mr. Lewandowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

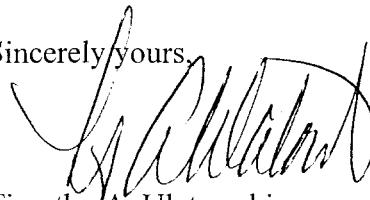
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski", written over the "Sincerely yours," text.

Timothy A. Ulatowski
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known):

Device Name: Ceramic Hextop Abutment

Indications For Use:

Ceramic hextop abutments are designed for use with commercially available osseointegrated dental implant systems. The abutments, which do not osseointegrate, are to be seated directly on top of the implant body. The abutments form the substructure of the restored prosthesis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Dental, Infection Control and General Hospital Devices

510(k) Number 1K0124B

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____

(Optional Format 1-2-96)

510 (k) Number (if known):

Device Name: ITI® Dental Implant System – Ceramic Coping

Indications For Use:

The ITI® ceramic coping is intended to be seated on the implant/abutment complex and serve as a base for the prosthetic reconstruction. The prefabricated coping provides a machined inner surface for mating with the abutment and implant, while the outer surface can be adapted to the individual restoration.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Dental, Infection Control and General Hospital Devices

510(k) Number

K012473

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____

(Optional Format 1-2-96)